

## **REMARKS**

Claims 20 and 31 are canceled in this paper. Claims 1, 5, 18, 19, 36 and 37 are amended in this paper. New claim 39 is added in this paper. Therefore, claims 1-19, 21-30, and 32-39 are pending. Of these claims, claims 4, 12, 16, 29 and 32-33 have been “withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected specie, there being no allowable generic or linking claim.” Accordingly, claims 1-3, 5-11, 13-15, 17-19, 21-28, 30 and 34-39 are under active consideration.

Claims 1-3, 5-10, 17-24, 27-28, 30-31 and 34-35 stand rejected under 35 U.S.C. 102(b) “as being clearly anticipated by Kelliher et al., US 5,836,924.” In support of the rejection, the Patent Office states the following:

Kelliher discloses a rotational feeding tube apparatus. See especially figures 1 and 5, showing the rotational valve. Regarding claims 7-10, although Kelliher is not intended for supporting a medical catheter, nothing in the claim structurally distinguishes for Kelliher. This interpretation is required by the MPEP. See MPEP 2114, which states that apparatus must be distinguished from the prior art in terms of structure rather than function. It is readily apparent that a medical catheter can be connected to the distal end opening 42. Regarding claim 10, the securing means can be a friction fit, which is shown by Kelliher.

Insofar as the subject rejection pertains to claims 20 and 31, the rejection is moot in view of Applicant’s cancellation of these claims. Insofar as the subject rejection pertains to claims 1-3, 5-10, 17-19, 21-24, 27-28, 30 and 34-35, Applicants respectfully traverse the subject rejection.

Claim 1 has been amended herein and now recites “[a]n adaptor well-suited for use with a medical catheter, said adaptor comprising:

(a) a tube support, said tube support being adapted for insertion into a medical catheter, the tube support having a lumen, said lumen being adapted for fluid communication with the medical catheter; and

(b) a tube, said tube being adapted for fluid communication with an external conduit, said tube being rotatable about its longitudinal axis between an open position in which said tube is in fluid communication with said lumen and a closed position in which said tube is not in fluid communication with said lumen; and

(c) means for securing a medical catheter to said tube support.”

Claim 1 is neither anticipated by nor rendered obvious over Kelliher et al. for at least the reason that Kelliher et al. does not teach or suggest an adaptor well-suited for use with a medical catheter, the adaptor comprising, among other things, a tube support adapted for insertion into a medical catheter and means for securing a medical catheter to said tube support.

Instead, Kelliher et al. is directed at a feeding apparatus, the Kelliher feeding apparatus including an external main retention portion (18/118) and a transverse flexible tube (40/140) with an internal retention balloon (48/148). As seen best in Fig. 3 of Kelliher et al., the transverse flexible tube is not inserted into a medical catheter, but rather, serves as the medical catheter, itself, with the internal retention balloon serving to retain the transverse flexible tube within a patient. Consequently, because the Kelliher flexible tube is not intended to be inserted into a medical catheter, there is no teaching or suggestion in Kelliher et al. to provide means for securing a medical catheter to said flexible tube.

Therefore, for at least the above reasons, claim 1 is patentable over Kelliher et al.

Claims 2-3 depend from claim 1 and are patentable over Kelliher et al. for at least the same reasons given above for claim 1.

Claim 5 has been amended herein and now recites “[a]n adaptor well-suited for use with a medical catheter, said adaptor comprising:

(a) a body, said body being provided with a first channel and a second channel, said first channel and said second channel being in fluid communication with one another, said first channel being adapted for fluid communication with the medical catheter, said second channel having a front end; and

(b) a stem, said stem having a front, a rear, a side wall, a cavity extending rearwardly from said front end, and a hole in said side wall in fluid communication with said cavity, said stem being mounted within said second channel of said body with said front end of said stem being spaced rearwardly from said front end of said second channel, said stem being rotatable between an open position in which said stem and said first channel are in fluid communication with one another via said hole and a closed position in which said stem and said first channel are not in fluid communication with one another.”

Claim 5 is neither anticipated by nor rendered obvious over Kelliher et al. for at least the reason that Kelliher et al. does not teach or suggest an adaptor well-suited for use with a medical catheter, the adaptor comprising, among other things, (i) a body provided with first and second channels, the second channel having a front end, and (ii) a stem rotatably mounted in said second channel, the stem having a front end spaced rearwardly from the front end of the second channel.

Instead, Kelliher et al. relates to a feeding apparatus, the Kelliher feeding apparatus comprising an external main retention portion (18/118) having a proximal end (24/124) and a valve

assembly (14/114) rotatably mounted in the external main retention portion (18/118). As clearly seen in Figs. 5 and 11 of Kelliher et al., the front end of the valve assembly extends forwardly beyond the proximal end of the external main retention portion.

Therefore, for at least the above reasons, claim 5 is patentable over Kelliher et al.

Claims 6-10, 17-19, 21-24, 27-28, 30 and 34-35 depend from claim 5 and are patentable over Kelliher et al. for at least the same reasons given above for claim 5. In particular, claim 10 is further patentable over Kelliher et al. for the reason that Kelliher et al. does not teach or suggest the desirability of securing its feeding apparatus to a medical catheter or means for effecting the same; claim 21 is further patentable over Kelliher et al. for the reason that Kelliher et al. does not teach or suggest externally threading the front end of the stem to engage a complementarily threaded sleeve; and claim 24 is further patentable over Kelliher et al. for the reason that Kelliher et al. does not teach or suggest shaping the exterior of the side wall of the stem to include a stop block and shaping the second channel to include a pair of stop surfaces, said stop block being engageable with said stop surfaces in such a way as to limit the range of rotation of said stem between said open and closed positions.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 11, 13-15 and 36-38 stand rejected under 35 U.S.C. 103(a) "as being unpatentable over Kelliher '924 as applied to claim 10 above, and further in view of Delegge, WO 02/13901."

In support of the rejection, the Patent Office states the following:

Kelliher discloses all of the claimed embodiments except for the ring-shaped member to secure the medical catheter. Kelliher discloses a one-piece bolster/valve apparatus with the bolster (Kelliher balloon 48) integrally connected to the valve 12. Applicant calls for a two-piece apparatus using a ring-shaped member to connect the bolster. Delegge exemplifies that ring-shaped securing

members are well-known in two-piece apparatuses. In addition, the examiner points out that ring-shaped securing nuts as illustrated by applicant are the most common method of attaching shut off valve members in plumbing tubes and have been around for ages. Accordingly, it would be obvious to one of ordinary skill in the art to attach a ring shaped member to make the Delegge apparatus separable instead of integral. In addition, it is well established that making a device separable as opposed to integral is prima facie obvious. See MPEP 2144.04 V.C., entitled "Making Separable." Regarding the claimed step increases for the outer diameter of the lower portion, it appears that Delegge discloses these features for optimally attaching the ring securement device.

Applicants respectfully traverse the subject rejection. Claims 11, 13-15 and 37-38 depend from claim 5. Claim 5 is patentable over Kelliher et al. for at least the reasons discussed above. DeLegge fails to cure all of the deficiencies of Kelliher et al. with respect to claim 5. Therefore, based at least on their respective dependencies from claim 5, claims 11, 13-15 and 37-38 are patentable over Kelliher et al. in view of DeLegge. In addition, claims 13-15 are further patentable over the applied combination of references for at least the reason that Kelliher et al. and DeLegge, taken individually or in combination, do not teach or suggest at least one step of increasing outer diameter on top of said tube support. DeLegge, contrary to the Patent Office's assertion, does not disclose a step of increasing outer diameter on top of a tube support, but rather, only discloses a threaded fitting 16. No steps are shown above DeLegge threaded fitting 16.

Furthermore, Applicants respectfully submit that there is no basis for combining Kelliher et al. and DeLegge in the manner proposed by the Patent Office. As explained above, Kelliher et al. is directed at a feeding apparatus that includes a flexible feeding tube (40/140) having an internal retention balloon (48/148). There would have been no reason for one of ordinary skill in the art to have attached another feeding tube to the distal end of flexible feeding tube (40/140) using a nut or

other securing device. In addition, to the extent that the Patent Office appears to be arguing that it would have been obvious to modify the Kelliher feeding apparatus from a “one-piece bolster/valve apparatus” to a two-piece apparatus, Applicants respectfully disagree. The balloon bolster of Kelliher is inextricably integrated into the design of the Kelliher apparatus. In order to convert the Kelliher apparatus to a two-piece apparatus, one would need to drastically re-design the Kelliher apparatus. The necessary guidance for doing so is not provided by the teachings of the prior art nor can it be gleaned by a mechanical application of MPEP 2144.04 V.C.

Finally, claim 36 is patentable over the applied combination of references for at least the same types of reasons discussed in the previous paragraph.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

Claims 25 and 26 stand rejected under 35 U.S.C. 103(a) “as being unpatentable over Kelliher ‘924 as applied to claim 5 above, and further in view of Shmulewitz et al., US 6,569,145.” In support of the rejection, the Patent Office states the following:

Kelliher discloses all of the claimed embodiments except for the window 53 to permit viewing of the valve position. Shmulewitz discloses that it is known to use a window 60 to show the position of a valve structure. See figures 5A, 5B, and column 7, line 8 of Shmulewitz. Accordingly, it would have been obvious to one of ordinary skill in the art to attach a window to the Kelliher apparatus so that it would have been visually apparent if the valve were open or closed as shown by Shmulewitz, for the purpose of confirming the valve position.

Applicants respectfully traverse the foregoing rejection. Claims 25 and 26 depend from claim 5. Claim 5 is patentable over Kelliher et al. for at least the reasons discussed above. Shmulewitz et al. fails to cure all of the deficiencies of Kelliher et al. with respect to claim 5.

Therefore, based at least on their respective dependencies from claim 5, claims 25 and 26 are patentable over Kelliher et al. in view of Shmulewitz et al.

Moreover, there is no basis for combining Kelliher et al. and Shmulewitz et al. in the manner proposed by the Patent Office. Kelliher et al., as noted above, is directed at a feeding apparatus. Shmulewitz et al., by contrast, is directed at a pressure-controlled continuous coronary sinus occlusion device. The valve structure of Shmulewitz et al. is entirely different from that of Kelliher et al. Moreover, whereas the Kelliher valve structure is disposed at the proximal end of the Kelliher feeding apparatus and is, therefore, easy to observe by an operator, the Shmulewitz valves 57a-57c are disposed at the distal end of the Shmulewitz occlusion device and are, therefore, difficult to observe by an operator. In view of these stark differences between the Kelliher and Shmulewitz devices, the Patent Office has failed to explain (i) why one of ordinary skill in the art would have been motivated to modify the Kelliher device to include a window and (ii) how the Kelliher device would have been modified to include such a window.

Accordingly, for at least the above reasons, the subject rejection should be withdrawn.

New claim 39 depends from claim 1 and is patentable over the prior art for at least the same reasons given above for claim 1.

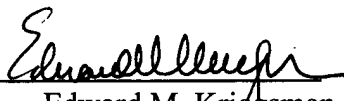
In conclusion, it is respectfully submitted that the present application is now in condition for allowance. Prompt and favorable action is earnestly solicited.

If there are any fees due in connection with the filing of this paper that are not accounted for, the Examiner is authorized to charge the fees to our Deposit Account No. 11-1755. If a fee is

required for an extension of time under 37 C.F.R. 1.136 that is not accounted for already, such an extension of time is requested and the fee should also be charged to our Deposit Account.

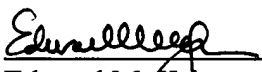
Respectfully submitted,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on February 21, 2005

  
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